

REMARKS

Applicants have cancelled claims 2-10, 12-17 and 25 without prejudice expressly reserving the right to pursue the subject matter of the cancelled claims in one or more subsequently filed applications.

Applicants have added claim 27, which is claim 14 rewritten in independent form incorporating all the limitations of claims 14 and claim 11 on which it depended.

Applicants have amended claim 1 to incorporate the features of claim 8, now cancelled, which previously depended on claim 1, and amended claims 22 and 23 to reflect the proper claim dependency.

Claims 1 and 9 are objected to for containing informalities. Applicant has cancelled claim 9 and revised claim 1 to correct the typographical error and thus have overcome the objection.

Claim 25 stands rejected under 35 U.S.C. 112, second paragraph for purportedly being indefinite. Applicants disagree but have cancelled claim 25 without prejudice solely to expedite prosecution and thus have obviated the rejection.

Claim 3 stands rejected under 35 U.S.C. 103(a) as purportedly being unpatentable over Dowson et al. in view of Kell et al. and further in view of *In Re Deuel*. Applicants disagree. However, claim 3 is now cancelled without prejudice solely to expedite prosecution, and as such Applicants have obviated the rejection.

Claims 1, 6, 8-10 and 24-26 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Dowson et al. in view of Kell et al. already

of record. In view of the following remarks, Applicant requests that the Examiner reconsider and withdraw the rejection.

The method of claims 1 and 24 comprises the step of hybridizing DNA from one species with probes for the same species, i.e., a DNA sample of *S. pneumoniae* is hybridized with more than one probe for a sequence that is specific to a PBP gene of a penicillin sensitive *S. pneumoniae* and more than one probe for a sequence that is specific to PBP gene of penicillin resistant *S. pneumoniae*. The claimed method allows a rapid, accurate discrimination between penicillin sensitive and penicillin resistant strains of *S. pneumoniae*.

In contrast, Dowson et al. disclose hybridizing DNA from one species to probes for a different species, i.e., hybridizing *S. sanguis* or *S. oralis* DNA to DNA probes specific for penicillin genes of *S. Pneumoniae*. Hence, Dowson et al. disclose hybridizing the DNA obtained from one species with probes specific for a different species.

Applicants point out that their claimed method requires not only multiple probes that specifically hybridize to sequences that are specific to penicillin binding proteins, but also requires that the isolated DNA, as well as the probes hybridizing thereto, be from the same species, i.e. *S pneumoniae*.

Dowson et al. would not motivate a person skilled in the art to generate the present invention because Dowson et al. teach a method to study the relatedness among different species; i.e. to identify the presence of a specific gene of one species in another species.

Because Dowson et al. teaches comparing different species with one another, Dowson et al. cannot suggest any desirability of hybridizing a DNA with probes from the same species without resorting to hindsight reconstruction based upon Applicant's claimed invention. In order to arrive at the claimed invention the method taught by Dowson et al. has to be modified so that DNA of *S.*

pneumoniae, instead of DNA of *S. sanguis* or *S. oralis*, is hybridized with probes to *S. pneumoniae*. However, this modification would render the method of Dowson unsatisfactory for Dowson's intended purpose, because hybridizing DNA of *S. pneumoniae* with probes to *S. pneumoniae* would not allow one of skill in the art to investigate the relatedness of *S. pneumoniae* with other different streptococci species. Hence, there is no suggestion or motivation to make such a modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

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Kell et al. do not overcome the deficiencies of Dowson et al. and thus Kell et al.'s combination with Dowson et al. fails to teach or suggest the invention as claimed.

Kell et al. teach that the PBP genes of resistant pneumococci have highly variable sequences (page 4388, right column) and, thus, are very diverse. Kell et al. study the relatedness among resistant pneumococci, but, Kell et al. do not teach or suggest a hybridization method that uses probes targeted to sequences specific for PBP genes of pneumococci. Rather, Kell et al. teach hybridizing DNA of two different organisms *pneumococci* and *E. coli*, particularly hybridizing restriction fragments of *pneumococci* DNA to ribosomal cDNA of *E. coli* (see page 4384, 3rd paragraph). Like Dowson et al., Kell et al. teach hybridizing pneumococci DNA with probes of *another* species. Therefore, Kell et al. teach away from hybridizing pneumococci DNA with DNA probes of pneumococci. Because Kell et al. do not teach or suggest using probes specific pneumococci, particularly the PBP genes of pneumococci, Kell et al. do not teach or suggest screening pneumococci with probes specific to PBP genes of pneumococci.

Both, Dowson et al. and Kell et al. teach screening a DNA sample from one species with probes of another species. Therefore, the combination of Dowson et al. and Kell et al. fails to teach or suggest hybridizing DNA of a pneumococci sample with DNA probes to the same pneumococci. As such the combination of Dowson et al. and Kell et al. fails to teach or suggest Applicant's invention as claimed.

As noted in Applicants' specification, and as taught by Dowson as well as Kell, penicillin resistance is highly diverse among strains. Therefore, a large number of resistance-specific probes would be needed to cover all possible kinds of resistance and such probes could not recognize unknown kinds of resistance. Applicants' claimed invention makes it possible to obtain an accurate test result by using only a few probes.

As illustrated in the present application, the claimed method, using only a few number of probes, results in a clear discrimination between resistant and sensitive samples (e.g. Fig. 2). In particular in the case of pneumococci hybridizing pneumococci DNA just two pneumococci penicillin sensitive-specific probes and just two pneumococci penicillin resistant-specific probes produce clear results.

In contrast, the method of Dowson et al. fails to discriminate between sensitive and resistant strains, because the probes to penicillin sensitive pneumococci do not bind to penicillin sensitive *S. oralis* and *S. sanguis* due to the genetic diversity between the different species.

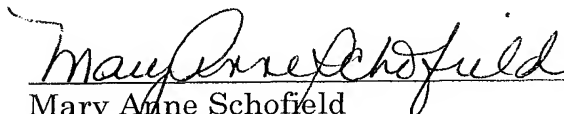
In view of the forgoing remarks, Applicants request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 103(a) in view of Dowson et al. and Kell et al.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 104049.B270037).

Respectfully submitted,

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